

**REMARKS/ARGUMENTS**

The Official Action has been carefully considered and the Examiner's comments are duly noted. Reconsideration is respectfully solicited.

In view of the fact that the Examiner issued a Final Action, Applicants' attorney should appreciate a courtesy telephone call to do what is necessary to place the Application into condition for allowance. Also, Applicants' are willing to cancel the withdrawn method claims and place them into a divisional application.

With respect to the disposition of the claims, items 4 and 6, claims 24 to 35 will be discussed. It should also be noted that claims 1, 2, 5, 15, and 17-19 and 21 are withdrawn claims. Claims 3, 4, 6-14, 16, 20 and 22-23 were cancelled. A previously withdrawn claim 20 was cancelled, but Applicant's reserve the right to file a divisional application.

With respect to the new matter rejection raised under the first paragraph following the claims rejection, "at least 3 cm in diameter" has been removed.

It should be noted that the science of tissue engineering is a new discipline and as such the terminology is being developed. Further, it is also well known that the drafter of this specification of Patent Application can be his/her own lexicographer. Therefore, since every item must have a "mass" the description of a culture for growing cells is sufficient to support a basis for isolated cell mass. As for the limitation "at least 3 mm", this has been removed even though it is not new matter when considering the relationship of this material and containers required to manufacture the construct. It is evident from the Examiner's comments at the top of page 3 of the specification regarding the diameter of the culture dish (page 17 of the specification) that 3.0 cm is an appropriate derivation to one skilled in the art regarding the structural size.

Not only is the material of what is in the four corners, but what a technical expert skilled in this art would know and every detail need not be specifically indicated if it is

known to one skilled in the art. In any event, the new matter objection is submitted as being overcome.

The Request for Continued Examination has been filed to avoid a delay on the basis that a new search may be necessary.

With respect to the objection on indefiniteness raised at the bottom of page 3, it is submitted that claim 24, as now amended, has removed these objections. Specifically, the construct has been further defined -- which is histologically competent for use with the human body both externally and internally --. This should overcome the indefiniteness as well as distinguish from the two references of record taken either singly or combined in any valid combination.

To replace the "3 mm in diameter", claim 24 was amended to define the structure as being "sufficient" and is a definite structural limitation. Regarding the scaffolding and the matrix, what is important is that with the present invention, there is no interaction with any scaffolding and/or a matrix and can be formed of cellular origin, which also distinguishes from the cited prior art.

Claim 24 is not a product by process claim even though there are characteristics which define the invention further. The Examiner's objection to "free of scaffolding and matrix" has been removed.

With respect to claims 33 and 34, these claims have been amended and claim 33 now includes the feature of "optionally" adding the features in claim 33, and claim 34 includes the limitation of claim 33, and this amendment should overcome the Examiner's objection.

Turning now to claim 26 and 30, claim 26 has been amended to substitute "without" for "free", and in lieu of comprising, and have the option of having the additional features in claim 26 and 30 added.

With respect to the rejection of claims 24-35 as being anticipated by Berg, U.S. Patent 5,755,814, the preamble as noted supra has been amended, and the preamble is a limitation in the claim.

Berg is concerned solely with the external skin or dermal portion or external portion of the body.

The publication by Katsuko S. Furukawa entitled -- Formation of Human Fibroblasts Aggregates (spheroids) by Rotational Culture -- while three dimensional because of spheroid technology is primarily intended for neonatal use which by itself is quite restrictive, and this publication specifically requires a biodegradable polymer mesh. The aggregates that were formed after shaking became or were attached to the polymer mesh. This group of experimenters, it would appear, were primarily concerned with a decrease, not an elimination of interaction between cells and substrates. See last five lines of column 2, page 443. Also, note the last six lines of column 2, page 446, which sets forth that the aggregates adhere to a biodegradable material. Clearly, this publication has no disclosure of a product free of a scaffold or a cellular material.

The U.S. Patent 5,755,814 also specifically is concerned with artificial skin and this is to be distinguished from diseased, damaged or other conditions.

The claims are directed to subject matter which is usable as an outer dermal layer, as well as an internal body organ. The Examiner should give patentable weight to the preamble of the claim because as the Examiner well knows the claim preamble is a limitation. Neither reference of record taken either singly or combined in any valid combination discloses or even has any appreciation of an internal organ. Therefore, claim 24 as amended is patentable over both references taken either singly or combined in any valid combination.

Claim 25, as amended, further is limited to the structural limitation as being free of any specific agents (structure) which aid in tissue formation and, therefore, exclude the specific agent from the tissue (structure) formation.

Claim 26, as amended, further specifically sets forth the exclusion of unnecessary structure.

Claim 28, as amended, includes the limitation free of dermal substitutes and, therefore, further defines the specific structure which distinguishes from the prior art.

Claim 31 was amended to remove 3 mm diameter as required by the Examiner.

Claim 33 was formally amended.

It should be further noted that the text of the specification refers to “tissue engineering” and further defines this term as beneficial tissues and organs. Derma or skin is not normally considered conventionally to be an organ. Organs are generally considered to be internal body parts whereas skin or derma is basically considered to be external. Since the Applicants can be their own lexicographer, with the aforesaid definition of “tissue” has a meaning totally and completely different from the two cited references, and their definition in the claims should be the same as used in the specification/description.

Further, with respect to the publication -- Formation of Human Fibroblasts Aggregates (spheroids) by Rotational Culture -- by Katsuko S. Furukawa, this publication is primarily concerned with a -- tissue-engineered skin product and while it goes into neo-natal products does not appear to meet all of the terms of the present Application.

Early and favorable reconsideration is respectfully solicited, together with the allowance of this Application.


A one-month term extension is respectfully requested to make this Request for Continued Examination timely filed. If any fees are necessary, please charge to our Deposit Account No. 50-3108. If for any reason there are insufficient funds in the Deposit Account, please charge to Deposit Account No. 10-0100.

The Examiner is also respectfully asked to call Applicants' attorney to do what is necessary to place this Application into condition for allowance and avoid a final rejection.

Respectfully submitted,

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